Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13336

0 - FRONT

To: Kathleen Cheeseman@OSN@FDA.CFSAN
From: Thaddeus Steinke@[redacted]@FDAORASWR
Certify: N
Subject: fwd: Adverse event (Stroke) related to "Total Control" with Ma
Date: Friday, February 12, 1999 at 10:06:16 am EST
Attached: None
Forwarded By: Thaddeus Steinke@[redacted]@FDAORASWR

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Comments By: Thaddeus Steinke@[redacted]@FDAORASWR
Originally To: Jim Kozick@LOS@FDAORAPAR
Originally Cc: Richard Aleman@DEN.IB@FDAORASWR, Margaret Annes@SLC.RP@FDAORASWR
Originally From: Thaddeus Steinke@[redacted]@FDAORASWR
Original Date: 2/11/99 5:53 PM
Comments:

As requested.

Ted Steinke, SCSO

----------[Original Message]----------

I just received a phone call from Jack Mitchell, Special Assistant to the Commisioner for Investigations, (301) 443-0492. He relayed information on an adverse event that had come to his attention regarding a product containing Ma Huang. He said that the information was for whatever followup we deemed necessary. He wanted to get the AE into our AE reporting system.

The product was a dietary supplement called "Total Control" from the firm Wesea, Park Blvd., San Diego, CA. This contains Ma Huang, with 22 mg. of ephedrine alkaloids per capsule. Other ingredients include Yohimbe and Cola Nut, plus a host of others. No code or lot number was available. He said the consumer still had the bottle plus the remaining capsules. Size was unknown.

Complainant identification: [redacted] Her husband is [redacted] Phone No.: [redacted]

Reportedly the woman was in good health and good physical condition with no known ailments and no history of high blood pressure. The label indications are up to 4 capsules a day, but reportedly the woman took 2 a day. I do not know how long the woman was on the medication. Reportedly on the day of the AE the woman took 2 capsules and then had a warm bath. She then suffered a serious stroke and was hospitalized. The doctor theorized that the product with ephedrine, plus the hot bath, may have elevated her blood pressure, causing the stroke. This event reportedly took place about 3 weeks ago. She was hospitalized locally, hospital ID unknown at this point.

Place of purchase is unknown at this point.

[redacted] plans to investigate this next week (we are currently short on manpower) and will collect the consumer's remaining portion, medical records and obtain additional information.

Ted Steinke, SCSO

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Adverse Event Questionnaire

Complaint Number: DEN-3805 CFSAN Project #13336 **Investigator:** Margaret M. Annes

Consumer Information

Date of Report: 02/11/99 MM/DD/YY

Initial Report Source: ☐ORA Consumer Injury
☐Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name [redacted] Gender: ☒F ☐M Age: 47

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 01/30/99
Previous Adverse Effects to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Home

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
Please refer to memo that this questionnaire is attached to.

How long did the symptoms last? Adverse event was a stroke
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). Product was taken daily (2 capsules - Sometimes 3) for approximately 9 months.) Product was used for weight management.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
Total Control

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☐No ☐Unknown – Single event occurred - Stroke
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: See medical records attached to memo re: CFSAN Project #13336

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? See medical records

What was the medical diagnosis? Stroke
What treatment(s) was given (e.g., drugs, other)? Patient on aspirin & atenolol - please refer to medical records

Were there any preexisting condition(s)/treatment(s)? NO
(If YES, list them including allergies, and chronic diseases): ☐Yes ☐No

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Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

Other Product Problems

2. ☐Foreign Object
(specify): _____

3. ☐Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label): Dosage: 1 capsule - 1-4x/day Not to exceed 4 capsules in a 24 hour period. Total Control - manufactured for: WesCa Naturals, 4452 Park Blvd., Suite #106, San Diego, CA 92116. No manufacturer listed.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown
Chromium picolinate, Spirulina, Ma Huang Extract, Citrus Aurantium, Kola Nut Extract, Yohimbe Extract, Green Tea Extract Ginseng Extract, Colloidal Minerals. - Each capsule contains 22mg Ephedrine Alkaloids per the label.

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☒Other Ma Huang
☐Unknown

☐Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☒Yes ☐No ☐Unknown
Product Sample Available: ☒Yes ☐No ☐Unknown
Sample #s 40892 & 40893 were collected.

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

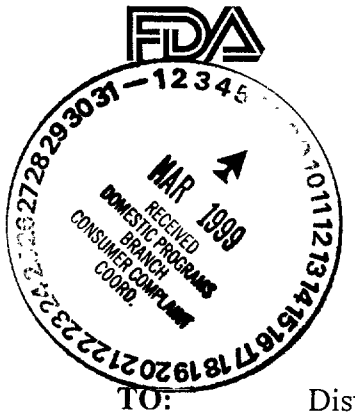
Death: ☐Yes ☒No

Life-Threatening: ☒Yes ☐No (MMA)

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) 1/30/99 - 2/13/99 - therapy ongoing

Required intervention to prevent permanent impairment/damage: ☒Yes ☐No - but there is some permanent damage due to stroke.

Did the adverse event result in a congenital anomaly: ☐Yes ☒No



HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
U.S. FOOD AND DRUG ADMINISTRATION

Denver District Office
[redacted]

TO: District Director, DEN-DO

FROM: Margaret M. Annes, CSO

DATE: March 2, 1999

Product: Total Control
(with Ma Huang)

Manufactured for:
WesCa Naturals
4452 Park Blvd., Suite 106
San Diego, CA 92116

SUBJECT: CFSAN Project #13336, Adverse Event Report; Follow-up to consumer complaint #DEN-3865, Total Control

On February 17, 1999, an investigation into an adverse event involving a woman from [redacted] was begun . The investigation was conducted due to the receipt of a follow-up assignment dated 2/17/99 from the Chief, Domestic Programs Branch, HFS-636, Division of Enforcement and Programs, CFSAN (Attachment #s 6.1-6.5). The request to conduct the follow-up came from CFSAN's Office of Special Nutritionals.

On February 11, 1999, Ted M. Steinke, [redacted] said that he had received a call from Jack Mitchell, Special Assistant to the Commissioner for Investigations, regarding an adverse event involving a product containing Ma Huang. A copy of the e-mail detailing this phone call is attached to this report (Attachment #2).

A 47-year-old woman had been using Total Control containing Ma Huang for approximately 9 months for weight management. She suffered a stroke, which the physician believes was related to the product. A portion of the consumer's remaining suspect product and an unopened bottle of a different lot number were collected as official samples (40892, 40893). No unopened containers of the suspect lot number were available, as the consumer received the product via mail order from WesCa Naturals, San Diego, CA. The samples were sent to SEA-DO Lab per initial instructions from CFSAN. However, analysis was held up pending further instructions from CFSAN regarding where the samples should be analyzed.

T. M. Steinke, SCSO
[redacted]

O: DEN-DO
cc: [redacted] HFS-636 (B. Wallace); LOS-DO; Complaint Coordinator (D. Bean); HFC-131 (J. Rowe – memo only – no attachments)

Memo 3/2/99 - CFSAN Project #13336, Adverse Event Report; Follow-up to consumer complaint #DEN-3865, Total Control

On February 16, 1999, Investigator Annes phoned Kathleen Cheeseman, Technical Information Specialist, CFSAN/OSN/CRRS, about the collection of a sample. She said to collect the consumer's sample per Dr. Lori Love, Director, Clinical Research & Review Staff, CFSAN/OSN. She was unsure of which lab to send the sample to, but said that she would get back to us on that. Later that same day, Investigator Annes received a message from Brenda Aloi, CFSAN, who said that the sample was to be sent to the Seattle Lab for analysis. Mr. Steinke confirmed this with Ms. Aloi on February 17, 1999.

On February 17, 1999, Investigators Margaret M. Annes and Juan A. Morales visited Mrs. [redacted] Mrs. [redacted] told us that she had purchased the product Total Control via mail order from a company in San Diego, California. The name of the company on the invoice (Attachment #7) is WesCa Naturals, 4452 Park Blvd., Suite 106, San Diego, CA 92116. The label on the product says that the product is manufactured for WesCa Naturals, but does not list the actual manufacturer. Mrs [redacted] said that she was using the product for weight loss since fen-phen had been taken off the market. Mrs. [redacted] had taken fen-phen for approximately 1 year and had stopped using it when it was taken off the market. Mrs. [redacted] explained to us that she had been taking the Total Control product for approximately 9 months (since May or June, 1998) and usually took 2 capsules per day. She said that on rare occasions she took 3 capsules.

On January 28, 1999, Mrs. [redacted] experienced what she termed "restless legs". She said that she got up from bed that evening and took some ibuprofen. The following day she went to work, but her legs kept bothering her, so she went to see a doctor. Mrs. [redacted] was seen at [redacted] The medical records are attached to this memo (Attachment #s 3.1-3.4). The doctor diagnosed the pain as due to tendonitis and per the medical records, she was told to take ibuprofen. Mrs. [redacted] says that there are several discrepancies in these medical records from [redacted], and has contacted her lawyer about how to proceed having them corrected. She said that she was not told to take ibuprofen and the doctor advised her to make an appointment for a complete physical exam. Mrs. [redacted] said that she made the appointment for Tuesday, February 2, 1999.

During the evening of January 29, 1999, Mrs. [redacted] said that she and her husband went out to dinner and when they returned home, they sat in the hot tub for approximately 5 minutes. Mrs. [redacted] said that she had stopped taking the Total Control on January 28, 1999 and did not take any of the capsules on January 29. At approximately 1:30a.m., Mrs. [redacted] said that she had difficulty with pain in her leg and got up from her bed and went to lay down on the couch in the living room. She said that she had difficulty walking to the couch. At approximately 3a.m., she got up to let the dog out and she fell down because she could not use the left side of her body. She said that she did not go to the emergency room until approximately 7:00a.m.

On January 30, 1999, Mrs. [redacted] went to [redacted] Her medical records are attached to this memo (Attachment #s 4.1-4.70). According to Mrs [redacted], they performed a CAT scan, which revealed that she had had a stroke. She was admitted into the hospital, and an MRI was performed, confirming the stroke. It was noted in her records that she had been taking an herbal product containing ephedrine (Attachment #s 4.3 & 4.5). Mrs. [redacted] said that there was a discrepancy in these medical records as well. She said that she did not drink 2-3 drinks per day of alcohol (Attachment #4.3) as noted.

Memo 3/2/99 - CFSAN Project #13336, Adverse Event Report; Follow-up to consumer complaint #DEN-3865, Total Control

On February 3, 1999, Mrs. [redacted] was discharged from [redacted] and transferred to [redacted] for stroke rehabilitation. The medical records from [redacted] are attached to this memo (Attachment #s 5.1-5.12). Mrs. [redacted] was discharged on February 13, 1999 from [redacted] to her home. She continues with outpatient therapy at [redacted]

A copy of the affidavit Mrs. [redacted] signed regarding the adverse event, the samples collected and other documentation obtained from her, is attached to this memo. The original affidavit is attached to the CR for sample #40892.

During our visit on February 17, 1999, Mrs. [redacted] and her husband said that they had contacted a lawyer. Their lawyer's name is [redacted] According to Mr. [redacted], Mr. [redacted] told them to refrigerate the product and to call the FDA. Mr. [redacted] also said that Mr. [redacted] had told them to hold onto the product themselves. Investigator Annes asked Mr. [redacted] if he would ask Mr. [redacted] to consider letting us (FDA) collect the product as well as the original container. Mr. [redacted] said that he would talk to Mr. [redacted] and get back to us on that matter.

On February 18, 1999, Mr. [redacted] called Investigator Annes and said that their attorney, Mr. [redacted] wanted to talk to us about the collection of the sample. Investigator Annes & SCSO Steinke spoke with Mr. [redacted] regarding chain of custody and it was agreed that we (FDA) could collect 25 of the remaining capsules and the original container.

Investigator Annes called Mr. [redacted], who informed her that Mrs. [redacted] would be out most of the afternoon and said that the sample of the Total Control product could be collected the next morning.

On February 19, 1999, Investigator Annes collected 2 samples from Mrs. [redacted]. One sample (#40892) consists of the consumer's bottle of Total Control (Lot #2693 EXP 2-01) with 25 capsules. The original bottle contained 90 capsules and 17 of the 42 capsules left were kept by Mrs. [redacted] The second sample (#40893) consists of an unopened bottle of Total Control (Lot #3154 EXP 7-01) which was in the consumer's possession. The two samples are from different lot numbers. This was all of the product in the consumer's possession. Since the product was ordered via mail, a sample with the same lot number as the consumer's opened bottle could not be collected. The samples were sent on February 26, 1999 to the Seattle Lab for analysis per CFSAN's original instructions.

The labeling on the unopened sample is slightly different from the opened sample in that the ingredients are slightly different. The Total Control (sample #40892) that the consumer had been taking was the newer of the two formulas according to her, and lists the ingredients as: Chromium Picolinate, Spirulina, Ma Huang Extract, Citrus Aurantium, Kola Nut Extract, Yohimbe Extract, Green Tea Extract, Ginseng Extract, Colloidal Minerals. Mrs. [redacted] said that she had received the "new" formula in her last shipment and began taking it then. The product came from the same company and had the same name as the product she had been taking before.

The other sample (#40893), is an unopened bottle of Total Control, which lists the ingredients as: Ma Huang Extract, Citrus Aurantium, Kola Nut, Yohimbe, Green Tea Extract, Ginseng, 77 Colloidal Minerals. The difference between the two products seems to be the addition of Chromium Picolinate

and Spirulina. This is the "old" formula that [redacted] had been taking until she received the new shipment. Mrs. [redacted] received a shipment of Total Control on November 30, 1998 (Attachment #7). Based on the number of capsules remaining in the opened bottle and the fact that Mrs [redacted] told us that her husband had taken a few of the capsules, the new formula (sample #40892) was received in that shipment. So, Mrs. [redacted] had been taking the old formula from May or June, 1998 until November, 1998 and the new formula from December, 1998 until the time of her stroke in January, 1999 (approximately 2 months).

On February 19, 1999, Investigator Annes spoke with Henry Carrillo, Consumer Complaint Coordinator, LOS-DO, regarding WesCa Naturals. Mr. Carrillo did a search of the OEI and did not find the company listed. Mr. Carrillo said that he searched the OEI using both the firm's name and address. He also checked the phone book and could not find a listing for the company.

ATTACHMENTS:

1. FDA 482 Notice of Inspection issued to [redacted] on 2/17/99
2. Copy of e-mail sent by T. Steinke, SCSO on February 11, 1999 regarding his phone conversation with Jack Mitchell about the adverse reaction. (1 page)
3. Medical records for [redacted] from [redacted] for 1/29/99 visit. (4 pages)
4. Medical records for [redacted] from [redacted] for 1/30/99-2/3/99. (70 pages)
5. Medical records for [redacted] from [redacted] for 2/3-13/99. (12 pages)
6. Assignment document from Chief, Domestic Programs Branch, HFS-636, Division of Enforcement and Programs, CFSAN dated February 17, 1999. (5 pages)
7. Copy of Invoice #2413 dated November 30, 1998 showing the receipt of Total Control (copies of this document are also attached to the CRs for sample #s 40892 & 40893). (1 page)
8. Copy of affidavit signed by [redacted] on 2/19/99. (4 pages)
9. Copies of labeling from sample #40892- opened consumer's portion of Total Control product. (6 pages)
10. Copies of labeling from sample #40893- unopened bottle of Total Control product. (3 pages)
11. Adverse Event Questionnaire (2 pages)

Margaret M. Annes

Margaret M. Annes, CSO
[redacted]
Denver District

Juan A. Morales

Juan A. Morales, CSO
[redacted]
Denver District